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Advisory Board on Radiation and Worker Health
National Institute for Occupational Safety and Health

A Review of NIOSH's Program Evaluation Report DCAS-PER-034, "Harshaw Chemical Company TBD Revision"

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Abbreviations and Acronyms

ABRWH, Board	Advisory Board on Radiation and Worker Health
AEC	Atomic Energy Commission
DCAS	Division of Compensation Analysis and Support
DR	dose reconstruction
HHS	U.S. Department of Health and Human Services
lb/d	pounds per day
Na_2UO_7	sodium uranate
NIOSH	National Institute for Occupational Safety and Health
ORAUT	Oak Ridge Associated Universities Team
PER	program evaluation report
POC	probability of causation
SEC	special exposure cohort
SPR	Subcommittee for Procedure Reviews
TBD	technical basis document
Th	thorium
UCl_4	uranium tetrachloride
UF_4	uranium tetrafluoride
UF_6	uranium hexafluoride
UNH	uranyl nitrate hexahydrate
$U(NO_3)^2$	uranium nitrate
UO_2	uranium dioxide
UO_2F_2	uranium oxyfluoride
UO_3	uranium trioxide
U_3O_8	triuranium octoxide
UX1	short-lived thorium

1 Statement of Purpose

To support dose reconstruction (DR), the National Institute for Occupational Safety and Health (NIOSH) and the Oak Ridge Associated Universities Team (ORAUT) assembled a large body of guidance documents, workbooks, computer codes, and tools. In recognition of the fact that all of these supporting elements in DR may be subject to revisions, provisions exist for evaluating the effect of such programmatic revisions on the outcome of previously completed DRs. Such revisions may be prompted by document revisions due to new information, misinterpretation of guidance, changes in policy, and/or programmatic improvements.

A program evaluation report (PER) provides a critical evaluation of the effects that a given issue or programmatic change may have on previously completed DRs. This includes a qualitative and quantitative assessment of potential impacts. Most important in this assessment is the potential impact on the probability of causation (POC) of previously completed DRs with POCs less than 50 percent.

During a teleconference by the Advisory Board on Radiation and Worker Health (Board) Subcommittee for Procedure Reviews (SPR) on March 14, 2024, the Board tasked SC&A to review DCAS-PER-034, revision 0, "Harshaw Chemical Company TBD Revision" (NIOSH, 2011). In conducting a PER review, SC&A is committed to perform the following five subtasks, each of which is discussed in this report:

- **Subtask 1:** Assess NIOSH's evaluation and characterization of the issue addressed in the PER and its potential impacts on DR. Our assessment intends to ensure that the issue was fully understood and characterized in the PER.

- **Subtask 2:** Assess NIOSH's specific methods for corrective action. When the PER involves a technical issue that is supported by documents (e.g., white papers, technical information bulletins, procedures) that have not yet been subjected to a formal SC&A review, subtask 2 will include a review of the scientific basis and/or sources of information to ensure the credibility of the corrective action and its consistency with current/consensus science. Conversely, if such technical documentation has been formalized and previously subjected to a review by SC&A, subtask 2 will simply provide a brief summary and conclusion of this review process.

- **Subtask 3:** Evaluate the PER's stated approach for identifying the universe of potentially affected DRs and assess the criteria by which a subset of potentially affected DRs was selected for reevaluation. The second step may have important implications, where the universe of previously denied DRs is very large and, for reasons of practicality, NIOSH's reevaluation is confined to a subset of DRs that, based on their scientific judgment, have the potential to be significantly affected by the PER. In behalf of subtask 3, SC&A will also evaluate the timeliness of the completion of the PER.

- **Subtask 4:** Conduct audits of DRs affected by the PER under review. The number of DRs selected for audit for a given PER will vary. (It is assumed that the Board will select the DRs and the total number of DR audits for each PER.)

- **Subtask 5:** Prepare a written report that contains the results of DR audits under subtask 4, along with our review conclusions.

2 Relevant Background Information Pertaining to Facility Operations, Potential Source Terms, and Worker Monitoring Protocols

2.1 Facility operations

The Harshaw Chemical Plant (Harshaw) in Cleveland, Ohio, received feed materials from various uranium mills throughout the United States and Canada and produced uranium compounds under U.S. Government contract from 1942 through 1955. A special exposure cohort (SEC) has been established for Harshaw employees who worked an aggregate of at least 250 days between August 14, 1942, and November 30, 1949. According to the SEC Petition Evaluation Report (Petition SEC-00066), Harshaw had serious deficiencies in bioassay monitoring prior to initiation of routine bioassay monitoring for uranium in December 1949. Regarding external monitoring, NIOSH concluded that DR from August 14, 1942, to November 30, 1949, was possible using film badge data and work area dose rate measurements (NIOSH, 2006).

Accordingly, SC&A's review of DCAS-PER-034 has considered the entire period from 1942 through 1955 for external dose, and the period December 1949 through 1955 for internal dose.

2.2 Source terms

Some of the major source terms at the Harshaw facility came from the following production processes according to revision 01 of ORAUT-TKBS-0022 (ORAUT, 2009, pp. 14–16).

2.2.1 Uranium tetrachloride production

Harshaw shipped its first order of uranium tetrachloride (UCl_4) to the National Bureau of Standards in March 1942. In November 1942, Harshaw began larger scale laboratory production of UCl_4 and a new production area was established in October 1944. In January 1945, the Manhattan Engineering District placed its final order of an additional 65,000 pounds of UCl_4. Harshaw stopped production of UCl_4 in February 1945 and the UCl_4 production area was dismantled.

2.2.2 Uranium hexafluoride production

Harshaw first produced uranium hexafluoride (UF_6) in February 1942 and maintained a production rate of five pounds per day (lb/d) throughout the year. By 1943, Harshaw was producing as much as 50 lb/d of UF_6 in a pilot plant, which operated until February 1944, producing a total of 9,000 pounds of UF_6.

In 1944, a new UF_6 production facility was built, which contained three units. Due to the increasing UF_6 production, an auxiliary building was added in 1945. By December 1947, Harshaw was producing up to 46,000 pounds of UF_6 per month. UF_6 production ended in December 1951.

2.2.3 Uranium tetrafluoride production

In 1942, Harshaw began to produce uranium tetrafluoride (UF_4) from uranium dioxide (UO_2). In July 1942, the Manhattan Engineering District asked Harshaw to produce 1,200 lb/d of UF_4 from UO_2.

In September 1942, Harshaw implemented large-scale production using a new facility with a production capacity of 50,000 pounds (25 tons) of UF_4 per month. Due to continued improvements in the conversion process, the production increased to 60 tons per month by December 1943. The final full production level for UF_4 (in February 1948) appears to have been 81 tons per month. In October 1951, production of UF_4 ceased.

2.2.4 Uranium trioxide and uranium dioxide production

In 1947, Harshaw constructed an ore-to-uranium trioxide (UO_3)-to-UO_2 batch production facility for the Atomic Energy Commission (AEC). This facility was constructed so UO_2 could be produced onsite, alleviating the need to bring in UO_2 from other suppliers. Production of UO_3 from ore continued until August 1953, when UO_3 production was placed on standby, and the AEC directed Harshaw to end all processing except for a final conversion of all leftover feed materials to UO_3.

2.2.5 Uranyl nitrate hexahydrate production

Throughout 1950 and 1951, uranyl nitrate hexahydrate (UNH), which is an intermediate liquid produced in the initial processing of ore and uranium extraction, was reportedly produced as research material at Harshaw. Based on available documentation, NIOSH could not determine if the UNH was produced for use at Harshaw or elsewhere. Beginning in 1952, Hanford sent UNH to Harshaw to be converted into UO_3. Hanford produced UNH using a tributyl phosphate chemical process and delivered it to Harshaw in tank cars.

2.2.6 Operations involving other radiological materials

Between 1943 and 1944, Harshaw manufactured several special radiological materials, including uranium oxyfluoride (UO_2F_2), sodium uranate (Na_2UO_7) at 84 percent, and uranium nitrate ($U(NO_3)^2$) at 56 percent (presumably the percentages were of triuranium octoxide (U_3O_8) equivalent). However, NIOSH has not located documentation describing how these materials were processed. Between February 1947 and August 1950, Harshaw produced short-lived thorium (Th)-234 (known as UX1) from a residue of the UF_4-to-UF_6 conversion process in a laboratory in bench quantities.

On at least two occasions, Harshaw processed some low-enriched uranium, in the form of UF_6, received from Hanford. This slightly enriched UF_6 appears to be enriched to less than one percent. NIOSH used a specific activity of 0.783 picocurie per microgram for one percent enriched uranium.

To estimate the activity fractions of recycled uranium contaminates at Harshaw during the period from July 1, 1952, to June 1954, the maximum radionuclide mass fractions were used with an assumption of specific activity for depleted uranium of 0.4 picocurie per microgram. Based on this assumption, the fractions listed in table 2-3 of the Harshaw site profile (ORAUT, 2009) will overestimate the activity of recycled uranium in the source term for most exposure scenarios.

2.3 Worker monitoring at Harshaw

The processing of uranium compounds at Harshaw, as outlined in section 2.2 of this report, produced source terms that resulted in potential internal and external radiation exposure to

workers from alpha particles, photons, electrons, and occasionally neutrons. A summary of internal, air, and external monitoring is provided in sections 2.3.1, 2.3.2, and 2.3.3 of this report.

2.3.1 Internal monitoring

As previously mentioned, an SEC has been established from August 14, 1942, through November 30, 1949, that has determined it is not feasible to assess internal dose due to the lack of internal dosimetry data for uranium radionuclides for operations at Harshaw. Beginning December 1, 1949, adequate information is available to perform an internal DR; however, there did not appear to be a routine bioassay program that included all potentially exposed workers at all times. Bioassay monitoring was instituted for certain locations or operations, but not necessarily on a continuous basis. Urinalysis data appeared to end in 1953 (ORAUT, 2009, pp. 20–24).

2.3.2 Air monitoring

There are no known radon measurements taken during the period of Harshaw operations. However, airborne radioactive dust samples for uranium were taken periodically at Harshaw starting in approximately 1943. The first formal program of airborne radioactive dust measurements was around 1948. Results of some of these measurements are summarized in tables B-10 through B-15 of the Harshaw site profile (ORUAT, 2009, pp. 91–98).

2.3.3 External monitoring

Beta dose and gamma dose to the extremities were potentially high for those workers handling hex ash and other residues. Film badging at Harshaw began in at least an intermittent fashion in August 1944, although it does not appear to have become routine until 1947. The earliest results appear to correspond to a badge start date of August 29, 1944. Although some improvements were instituted from 1942 to 1946, the start of routine film badging in 1947 is correlated with significant UF_4 and UF_6 production increases or with the peak of production, and the reports of external exposure problem occurred mostly after 1946. The AEC directive to badge all employees who might be subject to significant external exposure suggests to NIOSH that it is reasonable to assume that exposed employees at Harshaw will have at least some film badge results for their covered employment, and individuals with no badge results are unlikely to have received anything but incidental exposure. Individual dose histories are likely to contain gaps due to missing or damaged badges, especially for earlier periods (ORAUT, 2009, pp. 31–39).

As with internal monitoring, external monitoring was performed on an as-needed basis rather than a routine monitoring program for all employees.

No neutron exposure measurements are available for Harshaw. However, there were potential for neutron exposures at some locations and processes during certain time periods. Table B-8 of the site profile (ORAUT, 2009, p. 90) provides recommendations for neutron dose assignment, if appropriate.

3 Subtask 1: Identify the Circumstances that Necessitated DCAS-PER-034

3.1 Chronology of events

Harshaw SEC-00066: The Secretary of the U.S. Department of Health and Human Services (HHS) has designated a class of Harshaw workers for inclusion in the SEC for the period August 14, 1942, through November 30, 1949, in recognition of serious deficiencies in bioassay monitoring prior to initiation of routine bioassay monitoring for uranium in December 1949 (HHS, 2006).

ORAUT-TKBS-0022, revision 00: On August 17, 2007, NIOSH issued a site profile for Harshaw, revision 00 of ORAUT-TKBS-0022 (ORAUT, 2007), which was an exposure matrix to provide data and guidance for DR of Harshaw workers.

SC&A's Draft Review of ORAUT-TKBS-0022, revision 00: The Board tasked SC&A to conduct a technical review of revision 00 of ORAUT-TKBS-0022 (ORAUT, 2007). SC&A's (2008) review had findings that could impact the reconstruction of worker doses. One finding concerned the intake rates for type S uranium. Five other findings by SC&A pertained to NIOSH recommendations for internal and external DR.

ORAUT-TKBS-0022, revision 01: On June 2, 2009, NIOSH issued a site profile for Harshaw, ORAUT-TKBS-0022, revision 01 (ORAUT, 2009), which revised the intake rates for type S uranium.

DCAS-PER-034: On December 9, 2011, NIOSH issued DCAS-PER-034 for Harshaw to address changes in table 5-6, revision 00 of ORAUT-TKBS-0022 (NISOH, 2007) concerning type S uranium intake values, as outlined in finding 6 of SC&A's review.

March 14, 2024: The SPR tasked SC&A to review DCAS-PER-034.

3.2 SC&A's comments

SC&A agrees with NIOSH that the changes in the Harshaw site profile and their impacts on Harshaw worker doses mandate the need for DCAS-PER-034 (NIOSH, 2011).

There are no findings pertaining to subtask 1.

4 Subtask 2: Assess NIOSH's Specific Methods for Corrective Action

The publication record of revision 01 of the Harshaw site profile, ORAUT (2009, p. 2) acknowledged the following:

> Tables 5-6 and A-7 were modified and Figures A-3, A-4, A-5, A-8, A-9, and A-10 were replaced to correct an error in Rev 00. Figures A-1, A-2, A-6, and A-7 replaced to match the formatting of the modified figures. The footnote to Table B-25 was modified to clarify that the intakes listed are in terms of total alpha. The text in Section 5.9.5 was also modified to reflect this clarification. No comments were received as a result of formal internal review. Incorporates formal NIOSH review comments. Training required: As determined by the Objective Manager. Initiated by Eugene W. Potter.

In instances where the PER involves technical issues that are supported by a document that was previously reviewed by SC&A, subtask 2 will simply provide a brief summary/conclusion of this review process.

4.1 Overview of SC&A's previous review of revision 00 of ORAUT-TKBS-0022

SC&A reviewed revision 00 of ORAUT-TKBS-0022 (ORAUT, 2007) in May 2008 (SC&A, 2008). SC&A identified six findings and no observations. A summary of the six findings is as follows (SC&A, 2008, pp. 5–6):

> **Finding 1:** NIOSH proposes to use median values from lognormal distributions constructed from bioassay data for estimating internal exposures to workers from December 1949 through 1955. Since the median of a lognormal distribution always lies below the expected value (mean) of the distribution, the approach recommended by NIOSH is not claimant favorable. We propose the use of the 95 percent upper confidence bound on the lognormal mean as a more accurate representation of the expected values for the lognormal bioassay distributions and a more claimant-favorable metric.
>
> **Finding 2:** The site profile is silent regarding the conditions under which upper 95th percentile doses should be applied to workers who were not monitored, but who should have been monitored. Such an approach is appropriate for workers who may have regularly experienced high-end exposures due to their job category. In addition, the use of 95th percentile doses under appropriate circumstances is recommended in revision 01 of ORAUT-OTIB-0020 (ORAUT, 2005).
>
> **Finding 3:** In developing radon levels at Harshaw, where a sizeable amount of data are not available, NIOSH has used similar data from Mallinckrodt as a surrogate. However, the basis for selecting the surrogate data does not appear consistent and is not always claimant favorable.
>
> **Finding 4:** NIOSH needs to provide more detailed guidance on reconstruction of doses to extremities.

Finding 5: NIOSH needs to provide additional analysis of how the beta/photon doses were determined from film badges.

Finding 6: NIOSH needs to review its calculations of inhalation intakes of type S uranium derived from bioassay data. We believe that the reported numbers are low by about a factor of 5.

According to the Board Review System, findings 1 and 2 were resolved and closed by the SPR at the March 25, 2013, meeting. Findings 3 through 5 were resolved and closed by the SPR at the May 21, 2013, meeting. Finding 6 was addressed by NIOSH in revision 01 of ORAUT-TKBS-0022 (ORAUT, 2009) and sequent issuance of DCAS-PER-034 (NIOSH, 2011).

4.2 SC&A's review of revision 01 of ORAUT-TKBS-0022

SC&A's current review of ORAUT-TKBS-0022, revision 01 did not identify any new findings or observations. Additionally, SC&A compared ORAUT-TKBS-0022, revision 01 to ORAUT-TKBS-0022, revision 00 per verbatim and identified several small changes and editorial revisions that would not materially impact assigned dose, except for type S uranium intake values in table 5-6 (and table A-7). SC&A had previously performed the analysis of the data and made recommendations for the type S uranium intake values in table 6 of their 2008 review (SC&A, 2008). SC&A found that NIOSH concurred with SC&A's type S uranium intake values and the same intake values are used in tables 5-6 and A-7 of revision 01 of ORAUT-TKBS-0022 (ORAUT, 2009).

There are no findings associated with subtask 2.

5 Subtask 3: Evaluate the PER's Stated Approach for Identifying the Number of DRs Requiring Reevaluation of Dose

5.1 NIOSH's selection criteria

Section 3.0 of DCAS-PER-034 described the following criteria NIOSH used to identify previously completed claims requiring reevaluation using guidance in revision 01 of ORAUT-TKBS-0022 (ORAUT, 2009) and mandated by DCAS-PER-034 (NIOSH, 2011):

- POC less than 50 percent
- Most recent version of the DR approved by the Division of Compensation Analysis and Support (DCAS) on or prior to June 2, 2009 (date of Harshaw technical basis document (TBD), revision 01)
- Employed at Harshaw between December 1, 1949, and December 31, 1953.

These criteria were used to generate the list of six potentially affected claims.

NIOSH then removed one claim from this list of six claims because the intake was originally calculated using the individual's own bioassay data. The current revision of the TBD indicates these data should still be used, if available, so no change would occur to the dose estimate based on the TBD revision.

NIOSH then recalculated the dose for each of the remaining five claims using all current DR methods, including revision 01 of ORAUT-TKBS-0022 (ORAUT, 2009). From that recalculated dose, a new POC was determined. The new POC was less than 45 percent for each of the five claims. Therefore, none of the claims would now exceed a POC of 50 percent, and it was not necessary for NIOSH to request that the U. S. Department of Labor return any of the previously completed Harshaw claims based on the revision to the TBD.

5.2 SC&A's comments

SC&A finds that the selection criteria used by NIOSH for previously completed DRs that require reevaluation under DCAS-PER-034 are valid.

There are no findings associated with subtask 3.

6 Subtask 4: Conduct Audits of a Sample Set of Reevaluated DRs Mandated by DCAS-PER-034

Previous sections of this report described changes introduced in revision 01 of the Harshaw site profile (ORAUT, 2009) that increased the dose assigned for type S uranium.

For SC&A to satisfy its commitment under subtask 4, SC&A suggests that one of the five reworked DRs be selected for review where the worker was assigned type S uranium intake from table 5-6 of revision 01 of ORAUT-TKBS-0022 (ORAUT, 2009).

7 References

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